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10/772,101	02/04/2004	Jacques Seguin	CVALVE.006CP1	6184

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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/14/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/14/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/772,101	SEGUIN ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,12-16,31-33,36-45 and 79-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,12-16,31-33,36-45 and 79-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Attachments A, B*.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 13-16, 31-33, 36-40, 42, 44, 45, 79-86, 91-94, 96-104, 106, 108, and 110 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (U.S. Pub. No. 2002/0151970). Garrison et al. discloses the following regarding claim 1: a prosthetic valve assembly for use in replacing a deficient native cardiac valve, the valve assembly comprising: a prosthetic cardiac valve (6) having a base (40, 26, 28, 30, 31, 34), a plurality of commissure points (see Figure 10, 32), and a plurality of resilient leaflets (paragraph 0061) (Figure 10); a prosthetic cardiac valve support (8) configured to be collapsible for transluminal delivery (paragraph 0057) and comprising a first and a second portion (Attachment B), said first portion expandable to contact the anatomical cardiac annulus of the native cardiac valve when the cardiac valve assembly is properly positioned (paragraph 0058 indicates that the ends indicated in Attachment B flare the most to anchor in the walls of the vessel), said second portion supporting the base and the commissure points of the valve (see Attachment B); and a radial restraint (that struts that make up the support element 8) for controlling a diameter of the second portion (col. 5, lines 55-67) the radial restraint comprising a wire (see Figure 7; paragraph 0058,

lines 10-13); wherein the second portion has a smaller diameter than the first portion when the valve support is maximally expanded (see Figures 8, 9).

Garrison et al. discloses the limitations of claims 2-4 in paragraph 0069.

Garrison et al. discloses the following regarding claim 13: the prosthetic cardiac valve assembly further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment (paragraph 0080).

Garrison et al. discloses the following regarding claim 14: the cardiac valve assembly of wherein the valve support comprises at least one wire (see Figure 7).

Garrison et al. discloses the following regarding claim 15: the prosthetic cardiac valve wherein the valve support comprises a single length of wire (paragraph 0058).

Garrison et al. discloses the following regarding claim 16: the prosthetic cardiac valve assembly of Claim 15, wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force (see Figure 7, where the wire shown in capable of decreasing the radial expansion force). With this claim language, Applicant is not disclosing that the wire's thickness varies within the same length of the wire.

Garrison et al. discloses the following regarding claim 31: a prosthetic cardiac valve assembly configured for endoluminal delivery to replace a deficient native cardiac valve, the prosthetic cardiac valve assembly comprising an axial cardiac valve support portion (8) configured to support a prosthetic cardiac valve (6) having at least one leaflet (paragraph 0061; Figure 10) and to prevent substantial interference with the positioning and/or operation of the prosthetic cardiac valve by any residual components of the native cardiac valve, including calcified native cardiac valve components (paragraph 0056), said support portion comprising at

least one radial restraint (the struts that make up the support element 8) at a first section (see Attachment B) of said support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter (paragraph 0069) to increase coaptivity of the prosthetic cardiac valve leaflets and to prevent significant prosthetic cardiac valve regurgitation (paragraph 0056) and a second section (see Attachment B) configured to expand in situ for pushing the residual native cardiac valve components against the native annulus and surrounding tissue, wherein the second section is configured to expand to an expansion diameter different from an expansion diameter of the first section (see Figures 8, 9).

Garrison et al. discloses the following regarding claim 32: the prosthetic cardiac valve assembly wherein the radial restraint is configured to reduce recoil (paragraph 0080).

Garrison et al. discloses the following regarding claim 33: the prosthetic cardiac valve assembly wherein the radial restraint comprises a mechanical stop (paragraph 0080).

Garrison et al. discloses the following regarding claim 36: the prosthetic cardiac valve assembly wherein said second section is configured to be expanded by a balloon catheter (paragraph 0012).

Garrison et al. discloses the following regarding claim 37: the prosthetic cardiac valve assembly wherein said second section is configured to be expanded beyond its yield point in situ (paragraph 0069).

Garrison et al. discloses the following regarding claim 38: the prosthetic cardiac valve assembly further comprising a cardiac valvular ring stent (111) configured to expand in situ for pushing against the residual cardiac native valve components (see Figure 37).

Garrison et al. discloses the following regarding claim 40: the prosthetic cardiac valve assembly of Claim 38, wherein the cardiac valvular ring stent is configured to be expanded by a balloon catheter (paragraphs 0083, 0084).

Garrison et al. discloses the following regarding claim 42: the prosthetic cardiac valve assembly of Claim 38, wherein the cardiac valvular ring stent is configured to reside within the valve support portion when deployed (see Figure 37).

Garrison et al. discloses the following regarding claim 44: the prosthetic cardiac valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (paragraph 0080).

Garrison et al. discloses the following regarding claim 45: the prosthetic cardiac valve assembly wherein said radial restraint (12) comprises a wire (see Figure 7).

Garrison et al. discloses the following of claim 79: a prosthetic valve assembly for use in replacing a deficient native valve, the valve assembly comprising: a valve (6) having a base (40, 26, 28, 30, 31, 34), a plurality of commissure points (see Figure 10, 32), and a plurality of resilient leaflets (paragraph 0061; Figure 10); a valve support (8) configured to be collapsible for transluminal delivery (paragraph 0057) and comprising a single length of wire (paragraph 0058; see Figure 7), a first portion and a second portion (Attachment B), said first portion expandable to contact the anatomical annulus of the native valve when the assembly is properly positioned (paragraph 0058 indicates that the ends indicated in Attachment B flare the most to anchor in the walls of the vessel), said second portion supporting the base and the commissure points of the valve (50 or 54); and a radial restraint (the struts that make up the support element 8) for controlling a diameter of the second portion (col. 5, lines 36-41; Figures 1, 4, 6); wherein the

single length of wire has a reduced thickness to decrease the radial expansion force (see Figure 7, and explanation applied to claim 16, above).

Garrison et al. discloses the limitations of claims 80-82 in paragraph 0069.

Garrison et al. discloses the following regarding claim 83: the valve assembly wherein the radial restraint comprises a wire (see Figure 7; paragraph 0058).

Garrison et al. discloses the following regarding claim 84: the valve assembly wherein the radial restraint comprises a thread (see Figure 7; paragraph 0058).

Garrison et al. discloses the following regarding claim 85: the valve assembly wherein the radial restraint comprises a mechanical stop (paragraph 0080).

Garrison et al. discloses the following regarding claim 86: the valve assembly wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter (paragraph 0069).

Garrison et al. discloses the following regarding claim 91: the valve assembly, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment (paragraph 0080).

Garrison et al. discloses the following regarding claim 92: a prosthetic cardiac valve assembly configured for endoluminal delivery to replace a deficient native cardiac valve, the prosthetic cardiac valve assembly comprising an axial prosthetic cardiac valve support portion (8) configured to support a prosthetic cardiac valve (6) having at least one leaflet (paragraph 006; Figure 10) and to prevent substantial interference with the positioning and/or operation of the prosthetic cardiac valve by any residual components of the native cardiac valve, including calcified native cardiac valve components (paragraph 0056), said prosthetic cardiac support

portion comprising at least one radial restraint (the struts that make up the support element 8) at a first section of said prosthetic cardiac support portion (Attachment B) to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic cardiac valve leaflets and to prevent significant prosthetic cardiac regurgitation (paragraphs 0056 and 0069), and a second section (Attachment B) configured to expand in situ for pushing the residual native cardiac valve components against the native cardiac annulus and surrounding tissue (see Figures 8, 9), wherein the second section is configured to expand to a diameter different from that of the first section beyond its yield point in situ by a balloon catheter (paragraph 0069).

Garrison et al. discloses the following regarding claim 93: the prosthetic cardiac valve assembly further comprising a cardiac valvular ring stent (111) configured to expand in situ for pushing against the residual native valve components (see Figure 37).

Garrison et al. discloses the following regarding claim 94: the valve assembly wherein the stent is configured to reside within the valve support portion when deployed (see Figure 37).

Garrison et al. discloses the following regarding claim 96: the prosthetic cardiac valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (paragraph 0080).

Garrison et al. discloses the following regarding claim 97: the prosthetic cardiac valve assembly wherein said radial restraint comprises a wire (paragraph 0058; see Figure 7).

Garrison et al. discloses the following regarding claim 98: a prosthetic cardiac valve assembly configured for endoluminal delivery to replace a deficient native cardiac valve, the prosthetic cardiac valve assembly comprising an axial prosthetic cardiac valve support portion

(8) configured to support a prosthetic cardiac valve (6) having at least one leaflet (paragraph 0061) and to prevent substantial interference with the positioning and/or operation of the prosthetic cardiac valve by any residual components of the native cardiac valve, including calcified native cardiac components (paragraph 0056), said prosthetic cardiac support portion comprising at least one radial restraint (the struts that make up the support element 8) at a first section (Attachment B) of said prosthetic cardiac support portion to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic cardiac valve leaflets and to prevent significant prosthetic cardiac valve regurgitation (col. 6, lines 30-40), wherein said radial restraint comprises a wire (paragraphs 0069, 0080).

Garrison et al. discloses the following regarding claim 99: the prosthetic cardiac valve assembly wherein the radial restraint is configured to reduce recoil (paragraph 0069).

Garrison et al. discloses the following regarding claim 100: the prosthetic cardiac valve assembly wherein the prosthetic cardiac valve support portion further comprises a second section (Attachment B) configured to expand in situ for pushing the residual native cardiac valve components against the native annulus and surrounding tissue (paragraph 0056).

Garrison et al. discloses the following regarding claim 101: the prosthetic cardiac valve assembly wherein the second section is configured to expand to a diameter different from that of the first section (Attachment B; see Figures 7-10).

Garrison et al. discloses the following regarding claim 102: the prosthetic cardiac valve assembly wherein said second section is configured to be expanded by a balloon catheter (paragraph 0012).

Garrison et al. discloses the following regarding claim 103: the prosthetic cardiac valve assembly wherein said second section (52) is configured to be expanded beyond its yield point in situ (paragraph 0069).

Garrison et al. discloses the following regarding claim 104: the prosthetic cardiac valve assembly further comprising a cardiac valvular ring stent (111) configured to expand in situ for pushing against the residual native cardiac valve components (see Figure 37).

Garrison et al. discloses the following regarding claim 106: the valve assembly wherein the stent is configured to be expanded by a balloon catheter (paragraphs 0012, 0083, 0084).

Garrison et al. discloses the following regarding claim 108: the valve assembly wherein the stent is configured to reside within the valve support portion when deployed (see Figure 37).

Garrison et al. discloses the following regarding claim 110: the valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (paragraph 0080).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 79-86, 88, 90-93, 96-104, and 110 are rejected under 35 U.S.C. 102(b) as being unpatentable over Shaolian et al. (US Patent No. 6,299,637). Shaolian et al. discloses the following of claim 79: a prosthetic valve assembly (40) for use in replacing a deficient native valve (30), the valve assembly comprising (col. 2, lines 55-58): a valve having a base (see

attachment A), a plurality of commissure points (see attachment A), and a plurality of resilient leaflets (76, 78); a valve support (44) configured to be collapsible for transluminal delivery (col. 5, lines 36-37), and comprising a single length of wire (col. 6, lines 63-64), a first portion (52) and a second portion (54), said first portion expandable to contact the anatomical annulus of the native valve (30) when the assembly is properly positioned, said second portion supporting the base and the commissure points of the valve (50 or 54); and a radial restraint for controlling a diameter of the second portion (col. 5, lines 36-41; Figures 1, 4, 6); wherein the single length of wire has a reduced thickness to decrease the radial expansion force (see Figure 1, and explanation applied to claim 16, above).

Shaolian et al. discloses the following regarding claim 80: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter (col. 5, lines 55-60).

Shaolian et al. discloses the following regarding claim 81: the valve assembly wherein the radial restraint is capable of substantially resisting collapse below a preset diameter (col. 7, lines 6-10).

Shaolian et al. discloses the following regarding claim 82: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter (col. 5, 55-58; col. 7, lines 6-10).

Shaolian et al. discloses the following regarding claim 83: the valve assembly wherein the radial restraint comprises a wire (col. 6, 31-36).

Shaolian et al. discloses the following regarding claim 84: the valve assembly wherein the radial restraint comprises a thread (col. 6, 31-36).

Shaolian et al. discloses the following regarding claim 85: the valve assembly wherein the radial restraint comprises a mechanical stop ('637, col. 5, 63-67).

Shaolian et al. discloses the following regarding claim 86: the valve assembly wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter ('637, col. 5, 55-60; col. 7, lines 6-10).

Shaolian et al. discloses the following regarding claim 88: the valve assembly wherein the radial restraint comprises a cuff (50, 52, 54)(col. 6, lines 52-56; Figure 4).

Shaolian et al. discloses the following regarding claim 90: the valve assembly further comprising a drug-eluting component (col. 11, lines 9-12).

Shaolian et al. discloses the following regarding claim 91: the valve assembly, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment (col. 5, lines 60-67).

Shaolian et al. discloses the following regarding claim 92: a prosthetic cardiac valve assembly configured for endoluminal delivery to replace a deficient native cardiac valve (30) (col. 2, lines 55-58), the prosthetic cardiac valve assembly comprising an axial prosthetic cardiac valve support portion (50, 52, 54) configured to support a prosthetic cardiac valve (40) having at least one leaflet (76, 78) and to prevent substantial interference with the positioning and/or operation of the prosthetic cardiac valve (40) by any residual components of the native cardiac valve (30), including calcified native cardiac valve components (col. 5, lines 16-27), said prosthetic cardiac support portion comprising at least one radial restraint at a first section of said prosthetic cardiac support portion (50) to preclude expansion when deployed in situ substantially

no greater than a preset diameter to increase coaptivity of the prosthetic cardiac valve leaflets and to prevent significant prosthetic cardiac regurgitation (col. 6, lines 30-40), and a second section configured to expand in situ for pushing the residual native cardiac valve components against the native cardiac annulus and surrounding tissue (30), wherein the second section is configured to expand to a diameter different from that of the first section beyond its yield point in situ by a balloon catheter (col. 6, line 42, U.S. Pat. No. 5,800,508 incorporated by reference; col. 5, lines 37-49; Figures 1, 4, 6).

Shaolian et al. discloses the following regarding claim 93: the prosthetic cardiac valve assembly further comprising a cardiac valvular ring stent configured to expand in situ for pushing against the residual native valve components (col. 8, lines 39-42).

Shaolian et al. discloses the following regarding claim 96: the prosthetic cardiac valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (col. 5, lines 63-67).

Shaolian et al. discloses the following regarding claim 97: the prosthetic cardiac valve assembly wherein said radial restraint comprises a wire (col. 6, lines 30-36).

Shaolian et al. discloses the following regarding claim 98: a prosthetic cardiac valve assembly configured for endoluminal delivery to replace a deficient native cardiac valve (col. 2, lines 55-58), the prosthetic cardiac valve assembly comprising an axial prosthetic cardiac valve support portion configured to support a prosthetic cardiac valve (50, 52, 54) having at least one leaflet (76, 78) and to prevent substantial interference with the positioning and/or operation of the prosthetic cardiac valve by any residual components of the native cardiac valve (30, 40), including calcified native cardiac components (col. 5, lines 16-27), said prosthetic cardiac

support portion comprising at least one radial restraint at a first section of said prosthetic cardiac support portion (50) to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic cardiac valve leaflets and to prevent significant prosthetic cardiac valve regurgitation (col. 6, lines 30-40), wherein said radial restraint comprises a wire (col. 6, lines 30-36; Figures 1, 4, 6).

Shaolian et al. discloses the following regarding claim 99: the prosthetic cardiac valve assembly wherein the radial restraint is configured to reduce recoil (col. 5, lines 36-41, 49-54).

Shaolian et al. discloses the following regarding claim 100: the prosthetic cardiac valve assembly wherein the prosthetic cardiac valve support portion further comprises a second section (52) configured to expand in situ for pushing the residual native cardiac valve components against the native annulus and surrounding tissue (30) (col. 5, lines 37-49; Figures 1, 4).

Shaolian et al. discloses the following regarding claim 101: the prosthetic cardiac valve assembly wherein the second section (52) is configured to expand to a diameter different from that of the first section (50) (col. 5, lines 36-42; Figure 4).

Shaolian et al. discloses the following regarding claim 102: the prosthetic cardiac valve assembly wherein said second section is configured to be expanded by a balloon catheter (col. 6, line 42, U.S. Pat. No. 5,800,508 incorporated by reference).

Shaolian et al. discloses the following regarding claim 103: the prosthetic cardiac valve assembly wherein said second section (52) is configured to be expanded beyond its yield point in situ (col. 10, lines 58-60; Figure 4).

Shaolian et al. discloses the following regarding claim 104: the prosthetic cardiac valve assembly further comprising a cardiac valvular ring stent configured to expand in situ for pushing against the residual native cardiac valve components (col. 8, lines 39-42).

Shaolian et al. discloses the following regarding claim 110: the valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (col. 5, lines 63-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. et al. in view of Schwartz et al. (US Pub. No. 2002/0099439). Garrison et al. discloses the claimed invention except for a drug-eluting component that is included with the valve. Schwartz et al. teaches including such a compound with the valve to prevent cell overgrowth or extracellular matrix production (paragraphs 0014, 0023, 0083). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to include these drug eluding compounds with the valve to prevent cell overgrowth or extracellular matrix production.

Claims 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. in view of Kocur (US Patent No. 6,350,277). Garrison et al. discloses the use of a

stent with the valve system, but does not disclose all of the specific features of the stent as described by the applicant in claims 41 and 43.

Kocur discloses the following regarding claim 41: the valve assembly further composing a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26).

Kocur discloses the following regarding claim 43: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to these specifications to allow the stent to work more efficiently with the prosthetic valve system.

Claims 87 and 89, 95, 105, 107, and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. in view of Kocur (US Patent No. 6,350,277). Shaolian et al. does not disclose the use of a shape memory material as described by the applicant in claim 87. However, '277 teaches the use of nitinol, which is a shape memory material (col. 6, lines 36-39) that will assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory material such as nitinol to assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve.

Shaolian et al. does not disclose the use of stent specifically configured to cooperate with the valve support to preclude recoiling as described by the applicant in claim 89. However, '277

teaches the use of such a stent (col. 3, lines 16-26) to preclude recoil in the valve support. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to cooperate with the valve support system to preclude recoiling.

For claims 95 and 105, 107, and 109, Shaolian et al. discloses the use of a stent with the valve system, but does not disclose all of the specific features of the stent as described by the applicant in claims 95 and 105-109.

Kocur discloses the following regarding claim 95: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Kocur discloses the following regarding claim 105: the valve assembly wherein the stent is self-expanding (col. 3, lines 21-23).

Kocur discloses the following regarding claim 107: the valve assembly further comprising a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26).

Kocur discloses the following regarding claim 109: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to these specifications to allow the stent to work more efficiently with the prosthetic valve system.

Response to Arguments

Applicant's arguments filed 12/2/2006 have been fully considered but they are not persuasive. Applicant has added limitations to claims 1-4, 12-16, 31-33, 36-45, and 79-110, which define the claimed valve to be a prosthetic cardiac valve. Such language is directed toward the intended use of the valve. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitation. In addition, the definition of "cardiac" taken from the Merriam-Webster's Medical Dictionary states that it may be "of, relating to, situated near, or acting on the heart." From this definition, any valve acting within the proximity of the heart may qualify as a cardiac valve. And as shown in Andersen et al. (U.S. Pat. No. 5,840,081), Figures 8-10, valves such as the one described in Shaolian et al. could be situated in an area of close proximity to the heart.

Applicant's arguments with respect to claims 1 and 31, describing the expansion behavior of the valve, have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
January 9, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER

Attachment A

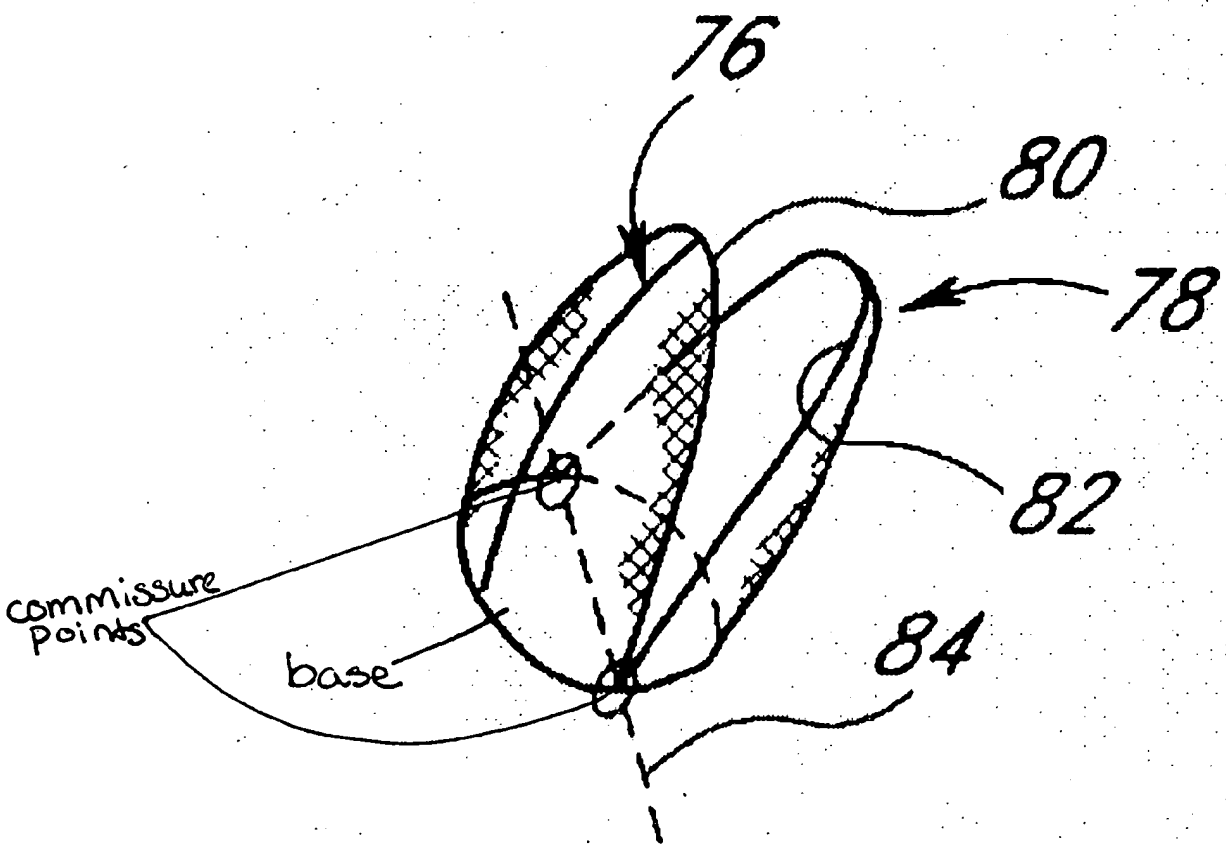

FIG. 6

Attachment B